510(k): K093324

MAR - 5 2010

Section 4: 510(k) Summary per 21 CFR 807.92

SUBMITTER: Empi Inc.
205 Hwy 22 East
Clear Lake, SD 57226

ESTABLISHMENT REGISTRATION: 1721293

CONTACT: Virginia L. Conger,
Director of Quality and Regulatory

PROPRIETARY NAME: Empi Continuum

CLASSIFICATION: Class II

PRODUCT CODES: IPF, Powered muscle stimulator
GZI, External functional neuromuscular
GZJ, Transcutaneous electrical nerve
LIH, Interferential current therapy
NYN, Stimulator, electrical, transcutaneous, for arthritis

REGULATION NUMBER: 21 CFR 890.5850

PANEL: Physical Medicine

Indications for Use:

As an NMES device, indications are for the following conditions:

- Retarding or preventing disuse atrophy
- Maintaining or increasing range of motion
- Re-educating muscles
- Relaxation of muscle spasms
- Increasing local blood circulation
- Prevention of venous thrombosis of the calf muscles immediately after surgery

As a TENS device, indications are for the following conditions:

- Symptomatic relief and management of chronic, intractable pain
- Adjunctive treatment for post-surgical and post-trauma acute pain
- Relief of pain associated with arthritis

As a Pulsed Current device, indications are for the following conditions:

- Reduction of edema (under negative electrode)
- Reduction of muscle spasm
- Influencing local blood circulation (under negative electrode)
- Retardation or prevention of disuse atrophy
- Facilitation of voluntary motor function
- Maintenance of increase of range of motion

As an FES device, the indications for the following condition:

- Stimulation of the leg and ankle muscles of partially paralyzed patients to provide flexation of the foot, thus improving the patient's GAIT.

Substantially Equivalent Predicate Devices

Predicate device(s):	300PV Complete Electrotherapy System
510(k) number:	K021100
Date:	June 18, 2002

Additional Predicate Devices:

Predicate device(s):	Empi SELECT TENS System
510(k) number:	K061650
Date:	February 22, 2007
Predicate device(s):	REHABILICARE IF 3 WAVE INTERFERENTIAL STIMULATOR SYSTEM
510(k) number:	K050046
Date:	April 13, 2005

Declarations of Conformity

The Empi Continuum devices comply with the following FDA recognized Consensus Standards:

- UL 60601-1: 2003, Standards for Medical Equipment Part 1: General Requirements for Safety, 1st Edition
- IEC 60601-1-2: 2001 +Amendment 1:2004, Medical Electrical Equipment Part 1 – 2: General requirements for Safety - Collateral Standard, Electromagnetic Compatibility – Requirements and Tests, 2nd Edition
- IEC 60601-2-10: 1987 +Amendment 1:2001, Medical Electrical Equipment - Part 2-10: Particular Requirements for the safety of nerve and muscle stimulator

Truthful and Accurate Statement

A statement attesting to the truthfulness and accuracy of the information was included in the premarket submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Empi, Inc.
c/o Mr. Jo P. Chiu, MS, MBA
Senior Regulatory Affairs Specialist
Chattanooga Group
4717 Adams Road
Hixson, TN 37343

MAR - 5 2010

Re: K093324
Trade/Device Name: EMPI Continuum
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: IPF
Dated: February 19, 2010
Received: February 24, 2010

Dear Mr. Chiu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K093324

Device Name: Empi Continuum

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Prescription Use √ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Tam L Kaus

(Division Sign-Off)

Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

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